

OCT 08 2002

Attachment 17  
510(k) Summary for the  
Family of Altus Medical CoolGlide Aesthetic Lasers

K02222b

**I. General Information**

Submitter: Altus Medical, Inc.  
821 Cowan Road  
Burlingame, CA 94010

Contact Persons: Kathy Maynor  
Mike Levernier

Summary Preparation Date: July 5, 2002

**II. Names**

Device Names: Family of Altus Medical CoolGlide Aesthetic Lasers

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories)

**III. Predicate Devices**

- Family of CoolGlide Aesthetic Lasers, manufactured by Altus Medical (K991798, K991234, K003202 and K014040);
- NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461);
- Vbeam and Clearbeam Pulsed Dye Lasers, manufactured by Candela (K013043 and K013748);
- PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806);
- CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715); and
- Smoothbeam Diode Laser, manufactured by Candela (K013825).
- Lyra Surgical Laser System, manufactured by Laserscope (K020021)

**IV. Product Description**

Family of Altus Medical CoolGlide Aesthetic Lasers are comprised of the following main components:

- a laser system console (including software and control electronics);
- a control and display panel;
- a permanently attached fiberoptic-coupled handpiece;
- a skin cooling device integrated into the handpiece;
- a footswitch (or finger-operated exposure switch (handswitch) option integrated into the handpiece)
- a remote interlock connector (disables laser when treatment room door is opened).

## V. **Indications for Use**

The family of Altus Medical CoolGlide Aesthetic Lasers are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

### **1064nm:**

#### **Dermatology:**

The Altus Medical Aesthetic CoolGlide laser systems are intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions, such as warts, scars, striae, and psoriasis. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The CoolGlide lasers are also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

The CoolGlide lasers are also indicated for the removal of unwanted hair, for stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB).

The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The intended use of the integral cooling system in the Altus CoolGlide laser handpiece is to provide cooling of the skin, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

**Surgical Applications:**

The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laprosopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

**Indications for use (532nm):**

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

**VI. Rationale for Substantial Equivalence**

The family of Altus Medical CoolGlide Aesthetic Lasers share the same general indications for use, and therefore is substantially equivalent to the currently marketed Altus Medical family of CoolGlide Aesthetic Nd:YAG Lasers (K991798, K991234, K003202 and K014040), the NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461), the Vbeam and Clearbeam Pulsed Dye Lasers, manufactured Candela (K013043 and K013748), the PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806), the CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715), the Smoothbeam Diode Laser, manufactured by Candela (K013825), and the Lyra Surgical Laser System, manufactured by Laserscope (K020021).

**VII. Safety and Effectiveness Information**

The new **indications for use** in dermatology, endoscopic/laprosopic general surgery, gastroenterology, general surgery, gynecology, otorhinolaryngology, neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary.thoracic surgery, and urology are based upon the indications for use for predicate laser systems.

Technologically, the CoolGlide family of aesthetic lasers is identical to the previous predicate CoolGlide family (K014040). Therefore the risks and benefits for the CoolGlide laser family are comparable to the predicate devices.

We therefore believe that there are no questions of safety or effectiveness raised by the introduction of this device.

## **VIII. Conclusion**

The family of Altus Medical CoolGlide Aesthetic Lasers were found to be substantially equivalent to the currently marketed Altus Medical family of CoolGlide Aesthetic Nd:YAG Lasers (K991798, K991234, K003202 and K014040), the NLite Pulsed Dye Laser, manufactured by ICN (K000811, K014130, and K013461), the Vbeam and Clearbeam Pulsed Dye Lasers, manufactured Candela (K013043 and K013748), the PhotoGenica Pulsed Dye Laser, manufactured by Cynosure (K012806), the CoolTouch I and CoolTouch II Nd:YAG lasers, manufactured by ICN (K014035 and K003715), the Smoothbeam Diode Laser, manufactured by Candela (K013825), and the Lyra Surgical Laser System, manufactured by Laserscope (K020021). The family of Altus Medical CoolGlide Aesthetic Lasers share similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 08 2002

Altus Medical, Inc.  
Michael Levernier  
Vice President, Clinical Development  
821 Cowan Road  
Burlingame, California 94010

Re: K022226

Trade/Device Name: Family of Altus Medical CoolGlide Aesthetic Lasers  
Regulation Number: 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: July 5, 2002  
Received: July 10, 2002

Dear Mr. Levernier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

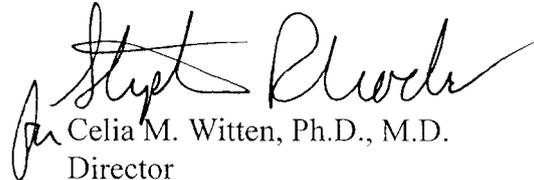
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Michael Levernier

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative  
and Neurological Devices**

510(k) Number K022226

Prescription Use    
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

**532nm:**

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and Neurological Devices

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